IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

ARTHURINE WILLIAMS, individually, as next of kin of and as Administrator of the estate of JOHNNY WILLIAMS, deceased,	)	
Plaintiff,	)	
vs.	)	**CASE NO.:**
FRESENIUS USA, INC., FRESENIUS USA MANUFACTURING, INC., FRESENIUS USA MARKETING, INC., FRESENIUS USA SALES, INC., FRESENIUS MEDICAL CARE HOLDINGS, INC., FRESENIUS MEDICAL CARE NORTH AMERICA, INC., and DAVITA, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiff, Arthurine Williams, by and through the undersigned counsel, files this complaint and hereby asserts as follows:

STATEMENT OF VENUE AND JURISDICTION

1. This Court has jurisdiction over this matter pursuant to 28 U.S.C. Section 1332, for diversity of citizenship and Plaintiff claims an amount in controversy exceeding $75,000.00.

2. A substantial amount of activity giving rise to the claims occurred in this District, the Plaintiff is a resident of this District, and Defendants each engaged in significant business

activities within this District. Therefore, venue is proper in this jurisdiction under 28 U.S.C. § 1391.

PARTIES

3. Decedent, Johnny Williams, at all relevant times hereto was a resident of the State of Alabama. Plaintiff, Arthurine Williams, is over the age of 19 years, is a citizen of the State of Alabama and the wife of the late Johnny Williams. Plaintiff is the duly appointed Administrator of the Estate as adjudicated in the Probate Court of Jefferson County, Alabama. In addition to her own individual interest, Plaintiff represents the interests of the Estate. The Decedent is survived by his children, grandchildren, and Plaintiff, Arthurine Williams. Plaintiff brings this action to recover damages for personal injuries sustained by decedent, Johnny Williams, after receiving dangerous dialysis treatment and for wrongful death.

4. Defendant, Fresenius USA, Inc. (collectively "Fresenius" with Defendants named in paragraphs 4-9), is a corporation of the state of Massachusetts with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451. At all relevant times herein, Fresenius was in the business of promoting, manufacturing, labeling, and distributing NaturaLyte® Liquid and Granuflo® Acid Concentrates. Defendant does business throughout the United States and at all relevant times hereto, marketed, promoted, warranted and sold NaturaLyte® Liquid and Granuflo® Acid Concentrates in Alabama.

5. Defendant, Fresenius Medical Care North America, Inc. (collectively "Fresenius" with Defendants named in paragraphs 4-9), is a corporation of the state of Massachusetts with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451. At all relevant times herein, Fresenius was in the business of promoting, manufacturing, labeling, and distributing NaturaLyte® Liquid and Granuflo® Acid Concentrates. Defendant does business

throughout the United States and at all relevant times hereto, marketed, promoted, warranted and sold NaturaLyte® Liquid and Granuflo® Acid Concentrates in Alabama.

6. Defendant, Fresenius USA Manufacturing, Inc. (collectively "Fresenius" with Defendants named in paragraphs 4-9), is a corporation of the state of Delaware with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451. At all relevant times herein, Fresenius was in the business of promoting, manufacturing, labeling, and distributing NaturaLyte® Liquid and Granuflo® Acid Concentrates. Defendant does business throughout the United States and at all relevant times hereto, marketed, promoted, warranted and sold NaturaLyte® Liquid and Granuflo® Acid Concentrates in Alabama.

7. Defendant, Fresenius USA Marketing, Inc. (collectively "Fresenius" with Defendants named in paragraphs 4-9), is a corporation of the state of Delaware with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451. At all relevant times herein, Fresenius was in the business of promoting, manufacturing, labeling, and distributing NaturaLyte® Liquid and Granuflo® Acid Concentrates. Defendant does business throughout the United States and at all relevant times hereto, marketed, promoted, warranted and sold NaturaLyte® Liquid and Granuflo® Acid Concentrates in Alabama.

8. Defendant, Fresenius USA Sales, Inc. (collectively "Fresenius" with Defendants named in paragraphs 4-9), is a corporation of the state of Delaware with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451. At all relevant times herein, Fresenius was in the business of promoting, manufacturing, labeling, and distributing NaturaLyte® Liquid and Granuflo® Acid Concentrates. Defendant does business throughout the United States and at all relevant times hereto, marketed, promoted, warranted and sold NaturaLyte® Liquid and Granuflo® Acid Concentrates in Alabama.

9. Defendant, Fresenius Medical Care Holdings, Inc. (individually as "FMC" and collectively as "Fresenius" with Defendants named in paragraphs 4-9), is a corporation of the state of New York with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451. At all relevant times herein, Fresenius was in the business of promoting, manufacturing, labeling, and distributing NaturaLyte® Liquid and Granuflo® Acid Concentrates. Defendant does business throughout the United States and at all relevant times hereto, marketed, promoted, warranted and sold NaturaLyte® Liquid and Granuflo® Acid Concentrates in Alabama.

10. Defendant DaVita, Inc. ("DaVita"), is a Delaware Corporation doing business in the state of Alabama and is in the business of providing dialysis treatment and dispensing dialysis concentrate products. At all times relevant to the allegations contained in this complaint, DaVita owned and operated the DaVita Ensley ("DaVita Ensley") dialysis clinic at 2630 Avenue E, Birmingham, Alabama 35218.

FACTS

11. This action arises from the use of NaturaLyte® Liquid and Granuflo® Acid Concentrates ("NaturaLyte" and "GranuFlo") in the dialysis treatment of decedent Johnny Williams and the resultant Heart Attack and Death that said use caused.

12. Fresenius Medical Care Holdings, Inc. is the largest division of Fresenius Medical Care AG, headquartered in Germany, and is the largest dialysis services and products company in both the U.S. and the world.

13. Fresenius is vertically integrated in its business environment in that Fresenius both owns thousands of dialysis clinics and it also manufactures the dialysis machines and nearly all the medical products used in dialysis care including dialyzers, blood lines, needles, dialysis

concentrate, etc.

14. The Fresenius products division "sells" products not only to its own clinics' division, but also sells them to many of its leading competitors, including DaVita, DCI, Renal Ventures, and many others.

15. Through information and belief, an internal memo from Fresenius dated November 4, 2011 indicated that Fresenius had knowledge that there was a significant increased risk of cardiac arrest and death during hemodialysis treatments associated with their Granuflo dialysis concentrate product that contains sodium diacetate.

16. Top Fresenius executives knew about the increased risk of cardiac arrest and death during hemodialysis treatments associated with their Granuflo dialysis concentrate product since the its introduction.

17. When a clinical problem finally became irrefutably evident to the Fresenius Medical Services division around 2010, top Fresenius executives chose not to properly report these complications or Granuflo specific risks to the FDA or other government agencies.

18. When the clinical problem finally became irrefutably evident to the Fresenius Medical Services division around 2010, top Fresenius executives also decided to withhold these complications or Granuflo specific risks from non-Fresenius physicians and clinics that were using the Granuflo product.

19. Through information and belief, there was collusion involving individuals in several Fresenius departments and organizations to hide, mislead, and obscure information about the extreme patient safety hazard associated with the use of Granuflo and NaturaLyte products in order to maintain their market share as well as to minimize and diffuse the legal risks for Fresenius.

20. Ultimately, after the correlation between Granuflo use, alkalosis, and cardiopulmonary arrest was made by Fresenius, the company chose to make this information, and associated urgent medical recommendations, solely available to its own physicians and clinics.

21. Through information and belief, the internal Fresenius memo which was circulated on November 4, 2011 specifically recommended action for patients with pre-dialysis bicarbonate levels of >28mEq/L and especially for those who also had pre-dialysis serum potassium levels of <4 mEq/L. This 6-page internal FMC memo shows that for at least 15 months, Fresenius did not share this information with the thousands of non-Fresenius physicians and clinics that were using the Granuflo product.

22. The November internal Fresenius memo went on to state that, "[r]ecent analyses performed using FMCNA hemodialysis (HD) patient safety data confirms that alkalosis is a significant risk factor associated with cardiopulmonary (CP) arrest in the dialysis unit, independent of and additive to the risk of CP arrest associated with pre-dialysis hypokalemia. The major cause of metabolic alkalosis in dialysis patients is inappropriately high dialysate total buffer concentration. As recommended in previous communications, physicians should individualized dialysate bicarbonate and total buffer prescriptions. We further recommend that predialysis serum bicarbonate level of >24 mEq/L should prompt immediate review of dialysate bicarbonate prescription."

23. The internal November memorandum went on to further state in its "summary of findings" that: "The current analysis determined that: "*borderline elevated pre-dialysis bicarbonate levels and over alkalosis are significantly associated with 6 to 8 fold greater increase of cardiopulmonary arrest and sudden cardiac death in the dialysis facility.*" (italics in

original)..."In light of these troubling findings, we strongly recommend that physicians adjust dialysate bicarbonate prescriptions monthly for individual patients, with immediate attention to patients with serum pre-dialysis bicarbonate level of >24 mEq/L." The memo further urges that this dangerous issue "needs to be addressed urgently."

24. On March 27, 2012, Fresenius received an inquiry from the FDA specifically about Granuflo-related products and alkalosis.

25. Only after the FDA inquiry did Fresenius provide a scientifically-ambiguous, 2-page memorandum, with far less actionable information, to its non-Fresenius customers. This correspondence did not mention any patient blood levels and failed to discuss in any manner the most at-risk population of all, "acute" dialysis patients.

26. The March 29th memo to non-Fresenius clinics and physicians contained only one of ten medical references that the FMC internal memo did. The March 29th memo also bundled the risks of Granuflo with another FMC acid concentrate product, NaturaLyte.

27. Through information and belief, the Granuflo product line saw steadily increased its market share since its introduction in 2003 and as of 2012 was used by the majority of nearly 400,000 hemodialysis patients in the U.S.

28. In the internal November 4, 2011 Fresenius memo, Granuflo use was associated with increased serum bicarbonate levels and alkalosis, as well as the increased possibility of cardiopulmonary arrests.

29. Also in the internal November 4, 2011 Fresenius memo, the company noted that its own patients' serum pre-dialysis bicarbonate levels had gradually increased from 2004 to 2011. Despite Fresenius' knowledge of this patient safety risk, more non-Fresenius clinics were actively being converted to the Granuflo product even after knowledge of the risks that were

made clear in the internal November 4, 2011 Fresenius memo.

30. Despite these patient safety issues and possible Federal Trade Commission and FDA violations and penalties, Fresenius product sales divisions continued to aggressively market the product and routinely bundled Granuflo with other Fresenius products for pricing discounts.

31. Granuflo formulations are unique in the dialysis treatment world in that they use sodium diacetate. Through this formulation, Granuflo doubles the amount of acetate in dialysate compared to formulations made with acetic acid. Instead of adding 4 mEq/L of acetate, it adds 8mEq/L. This means that for dialysates made from Granuflo, the total buffer level is 8 mEq/L higher than the bicarbonate level delivered from the bicarbonate concentrate.

32. This increased buffer level with Granuflo products was never communicated by Fresenius to treating clinicians, physicians, or nurses and could lead to significantly increased bicarbonate levels and the associated risks of heart attack, cardio pulmonary arrest, and/or sudden cardiac death.

33. DaVita owns and operates over 1,600 dialysis clinics in the United States and is one of the largest providers of in-center dialysis treatment in the world.

34. DaVita employs, trains, and/or contracts with the individual clinicians, nurses, and physicians who work in each of its individual in-center dialysis facilities.

35. DaVita entered into contracts with Fresenius to purchase, prepare, and use the Granuflo and NaturaLyte products for hemodialysis treatments in each of its over 1,600 in-clinic facilities. This included, but was not limited to, the DaVita Ensley facility where Johnny Williams was treated in 2010.

36. DaVita is responsible for ensuring (through adequate training, instruction, monitoring, and hiring principles) that its clinicians, nurses, and physicians know how to

properly use all hemodialysis products in a manner that is safe and effective for the recipients.

37. Lacking clinical knowledge, as well as a lack of effective product-related labeling, warning, and instruction from Fresenius, resulted in treating clinicians, physicians, and/or nurses providing hemodialysis treatments to patients in a manner that was neither safe nor effective.

38. Through information and belief, Decedent, Johnny Williams, was prescribed Granuflo and NaturaLyte three times a week beginning in June 2010.

39. On July 28, 2010, Johnny Williams received hemodialysis treatment at DaVita Ensley. He was provided with Granuflo during this treatment.

40. Decedent, Johnny Williams, relied upon the misrepresentations and actions of Defendants Fresenius and DaVita in so far as that the hemodialysis products he was being provided were safe and effective for use in his treatments.

41. Decedent, Johnny Williams, relied upon the misrepresentations and actions of Defendant DaVita in so far as that the clinicians, physicians, and/or nurses were adequately trained, instructed, credentialed, and prepared for proper use of all hemodialysis products in a manner that was safe and effective.

42. After using the Fresenius Granuflo product at DaVita Ensley, Decedent, Johnny Williams, suffered from a sudden heart attack and died on July 29, 2010.

COUNT I
STRICT LIABILITY (AEMLD)

43. Plaintiff adopts and incorporates by reference all the above allegations.

44. At all times material hereto, the Defendants Fresenius and DaVita engaged in the business of selling, distributing, manufacturing, marketing, labeling, and/or promoting NaturaLyte and GranuFlo, which are unreasonably dangerous, and therefore defective. These

products were defective because they were more dangerous than would be reasonably contemplated by the ordinary user.

45. At all times material hereto, NaturaLyte and GranuFlo reached Johnny Williams without substantial change in the condition in which they left the possession of the Defendants and were used in manner which had been contemplated.

46. NaturaLyte and GranuFlo were defective and unreasonably dangerous when they entered the stream of commerce and were received by Johnny Williams because:

a. NaturaLyte and GranuFlo contained manufacturing defects in that they can cause heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions.
b. NaturaLyte and GranuFlo were not safe as designed, taking into account that the foreseeable risks involved in their use outweighed their utility and therapeutic benefits.
c. NaturaLyte and GranuFlo were marketed and promoted for use in hemodialysis treatment, when they carried an unreasonable and unnecessary risk of serious injury. The risk of harm far outweighed the benefit of use.
d. NaturaLyte and GranuFlo were insufficiently and inadequately tested, yet Defendants promoted them as being tested and safe for use.
e. NaturaLyte and GranuFlo were not safe due to inadequate and defective instructions and warnings at the time it left the possession of the Defendants. The warnings were inadequate to fully apprise the user and health care providers of the full nature and extent of the risks and dangerous side effects associated with the use;
f. NaturaLyte and GranuFlo were marketed and promoted for use as safe treatment in hemodialysis treatment, when they were not.

47. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Johnny Williams has sustained injuries and is entitled to damages enumerated below. Johnny Williams' damages were not caused by an inherent characteristic of dialysis treatment that cannot be eliminated, but instead were caused by the products used being dangerously defective as outlined above.

48. Defendants' actions and inactions as set forth above were intentional and

deliberate, and resulted in the death of Johnny Williams.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiff demands judgment of the Defendants, Fresenius and DaVita, for damages in an amount determined by the jury and such other and further relief as allowed in equity or law.

COUNT II
FAILURE TO WARN

49. Plaintiff adopts and incorporates by reference all the above allegations.

50. NaturaLyte and GranuFlo can be unreasonably dangerous, even when used for its intended purpose.

51. Defendants Fresenius, one of the world's largest manufacturers of dialysis concentrate products, is held to the level of knowledge of an expert in the field, and further, Defendants Fresenius had knowledge of the dangerous risks and side effects of NaturaLyte and GranuFlo of which it failed to warn Johnny Williams, and/or protect him by informing Defendant DaVita.

52. Defendant DaVita, one of the largest dialysis providers in the world, is held to the level of knowledge of an expert in the field, and further, Defendant DaVita had knowledge of the dangerous risks and side effects of NaturaLyte and GranuFlo, or similar dialysis concentrates, of which it failed to warn Johnny Williams and/or protect him.

53. Johnny Williams did not have the same knowledge as Defendant and no adequate warning was communicated to Plaintiff.

54. Defendants Fresenius had a continuing duty to warn consumers, including Johnny Williams, and providers, including Defendant DaVita, of its products, and the risks and dangers associated with them, and negligently and/or wantonly breached its duty as follows:

a. Failed to include adequate warnings with the hemodialysis products that would alert consumers to the dangerous risks and serious side effects of NaturaLyte and GranuFlo.
b. Failed to provide adequate post-marketing warnings and instructions after the Defendants knew or should have known of the significant risks of heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions from the use of NaturaLyte and GranuFlo.
c. Failed to inform Plaintiff that NaturaLyte and GranuFlo had not been adequately and thoroughly tested for safety as a hemodialysis treatment.

55. Defendant DaVita had a continuing duty to warn consumers, including Johnny Williams, of the dialysis concentrate products being used, and the risks and dangers associated with them, and negligently and/or wantonly breached its duty as follows:

a. Failed to include adequate warnings with the hemodialysis products that would alert consumers to the dangerous risks and serious side effects of NaturaLyte and GranuFlo.
b. Failed to provide adequate post-marketing warnings and instructions after the Defendant knew or should have known of the significant risks of heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions from the use of NaturaLyte and GranuFlo.
c. Failed to inform Plaintiff that NaturaLyte and GranuFlo had not been adequately and thoroughly tested for safety as a hemodialysis treatment.
d. Failed to inform Plaintiff that the DaVita clinicians, nurses, and/or physicians were not adequately trained, instructed, credentialed, and prepared for proper use of all hemodialysis products in a manner that was safe and effective.

56. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Johnny Williams sustained injuries and died.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiff demands judgment of the Defendants, Fresenius and DaVita, for damages in an amount determined by the jury and such other and further relief as allowed in equity or law.

COUNT III
BREACH OF WARRANY OF MERCHANTABILITY

57. Plaintiff adopts and incorporates by reference all the above allegations.

58. When Defendants Fresenius placed NaturaLyte and GranuFlo into the stream of commerce, they knew that the dialysis concentrates would be used for dialysis treatments just as Johnny Williams received, and expressly and impliedly warranted to Plaintiff that use of NaturaLyte and GranuFlo was a safe and acceptable means of receiving dialysis treatment.

59. When Defendant DaVita mixed the NaturaLyte and GranuFlo and provided it to Johnny Williams, it knew that the dialysis concentrates would be used for dialysis treatments just as Johnny Williams received, and expressly and impliedly warranted to Plaintiff that use of NaturaLyte and GranuFlo was a safe and acceptable means of receiving dialysis treatment.

60. Johnny Williams reasonably relied upon the expertise, skill, judgment and knowledge of the Defendants and upon the express and/or implied warranty that NaturaLyte and GranuFlo was of merchantable quality and fit for use to treat bone loss.

61. In fact, NaturaLyte and GranuFlo were not of merchantable quality and were not safe or fit for their intended use because they were unreasonably dangerous and unfit for the ordinary purposes for which they were used, in that NaturaLyte and GranuFlo caused serious injuries and damages. NaturaLyte and GranuFlo breached the warranties because they were unduly dangerous in expected use and did cause undue injuries and the death of Johnny Williams.

62. As a direct and proximate result of the breach of warranties by the Defendant, Johnny Williams sustained injuries and died.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiff demands judgment of the Defendants, Fresenius and DaVita, for damages in an amount determined by the jury and such other and further relief as allowed in equity or law.

COUNT IV
NEGLIGENCE AS TO DEFENDANTS FRESENIUS

63. Plaintiff adopts and incorporates by reference all the allegations above.

64. Defendants Fresenius negligently manufactured, designed, tested, researched and developed, labeled, packaged, distributed, promoted, marketed, advertised, and sold NaturaLyte and GranuFlo in the state of Alabama.

65. At all times material hereto, Defendants Fresenius had a duty to exercise reasonable care in the design, manufacture, research and development, testing, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of NaturaLyte and GranuFlo.

66. Defendants Fresenius breached their duty and were negligent in their actions, misrepresentations, and omissions toward Johnny Williams in the following ways:

a. Failing to test and inspect NaturaLyte and GranuFlo in a reasonable manner in order to ascertain whether or not it was safe and proper for the purpose for which it was designed, manufactured, and sold;
b. Failing to utilize and implement a reasonably safe design in the manufacture of NaturaLyte and GranuFlo;
c. Failing to manufacture NaturaLyte and GranuFlo in a reasonably safe condition;
d. Failing to warn the Plaintiff of the danger of heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions from the use of NaturaLyte and GranuFlo;
e. Failing to label NaturaLyte and GranuFlo reasonably so as to warn the Plaintiff of the danger of heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions from the use of NaturaLyte and GranuFlo; and
f. Manufacturing NaturaLyte and GranuFlo, which are unreasonably dangerous and defective hemodialysis products.

67. Defendants Fresenius knew or should have known that NaturaLyte and GranuFlo had unreasonably dangerous risks and caused serious side effects of which Plaintiff would not be

aware. Defendants Fresenius nevertheless advertised, marketed, sold and distributed NaturaLyte and GranuFlo knowing that there were safer methods and products for dialysis treatment.

68. Furthermore, Defendants Fresenius are guilty of negligence *per se*. Novartis violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq*., and the Sherman Food, Drug and Cosmetic Law, as well as other applicable laws, statutes, and regulations. Novartis' acts and omissions constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §331. This is negligence *per se*.

69. Defendant Fresenius failed to meet the standard of care set forth by the following statutes and regulations. Legislators enacted these statutes and regulations for the benefit of a specific class of citizens. The Plaintiff is part of this class. Therefore, Defendants Fresenius are negligent *per se* in the following respects:

a. The labeling lacked adequate information on the use of NaturaLyte and GranuFlo (21 C.F.R. Section 201.56[a] and [d]);
b. The labeling failed to provide adequate warnings of severe and disabling medical conditions including, without limitations, heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions as soon as there was reasonable evidence of their association with NaturaLyte and GranuFlo (21 C.F.R. 201.57[e]);
c. There was inadequate information for patients for the safe and effective use of NaturaLyte and GranuFlo (21 C.F.R. 201.57[f][2]);
d. There was inadequate information regarding special care to be exercised by the doctor or clinician for safe and effective use of NaturaLyte and GranuFlo (21 C.F.R.201.57[f][2]); and
e. The labeling was misleading and promotional (21 C.F.R. 201.56[b]).

70. As a direct and proximate result of the negligent actions and inactions of the Defendants as set forth above, Johnny Williams sustained injuries and died.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiff demands judgment of the Defendants Fresenius for damages in an amount determined by the jury and such other and further relief as allowed in equity or law.

COUNT V
NEGLIGENCE AS TO DEFENDANT DAVITA

71. Plaintiff adopts and incorporates by reference all the allegations above.

72. Defendant DaVita negligently mixed, distributed, promoted, marketed, advertised, and sold NaturaLyte and GranuFlo in the state of Alabama.

73. At all times material hereto, Defendant DaVita had a duty to exercise reasonable care in the mixing, distribution, promotion, marketing, advertising, and sale of and NaturaLyte and GranuFlo.

74. Defendant DaVita negligently trained and instructed its dialysis employees, providers, and/or clinicians on the proper procedures for implementing NaturaLyte and GranuFlo in dialysis treatments in the state of Alabama.

75. At all times material hereto, Defendant DaVita had a duty to exercise reasonable care in the training and instruction of its dialysis employees, providers and/or clinicians on the proper procedures for implementing NaturaLyte and GranuFlo in dialysis treatments

76. Defendant DaVita breached their duty and were negligent in their actions, misrepresentations, and omissions toward Johnny Williams in the following ways:

a. Failing to test and inspect NaturaLyte and GranuFlo in a reasonable manner in order to ascertain whether or not it was safe and proper for the purpose for which it was designed, manufactured, and sold;
b. Failing to warn the Plaintiff of the danger of heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions from the use of NaturaLyte and GranuFlo; and
c. Failing to insure DaVita clinicians, nurses, and/or physicians were adequately trained, instructed, credentialed, and prepared for proper use of all hemodialysis products in a manner that was safe and effective.

77. Defendant DaVita knew or should have known that NaturaLyte and GranuFlo had unreasonably dangerous risks and caused serious side effects of which Plaintiff would not be

aware. Defendant DaVita nevertheless sold and distributed NaturaLyte and GranuFlo knowing that there were safer methods and products for dialysis treatment.

78. Defendant DaVita knew or should have known that its employees, contractors, clinicians, physicians, and/or nurses were not adequately trained, instructed, credentialed, or prepared to use NaturaLyte and GranuFlo in hemodialysis treatment without dangerous risks and serious side effects of which Plaintiff would not be aware. Defendant DaVita nevertheless sold and distributed NaturaLyte and GranuFlo knowing that DaVita employees, contractors, clinicians, physicians, and/or nurses were not adequately trained, instructed, credentialed, or prepared to safely and effectively use NaturaLyte and GranuFlo.

79. As a direct and proximate result of the negligent actions and inactions of the Defendant as set forth above, Johnny Williams sustained injuries and died.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiff demands judgment of the Defendants DaVita for damages in an amount determined by the jury and such other and further relief as allowed in equity or law.

COUNT VI
WANTONNESS

80. Plaintiff adopts and incorporates by reference all the allegations above.

81. Defendants Fresenius wantonly and recklessly manufactured, designed, tested, researched and developed, labeled, packaged, distributed, promoted, marketed, advertised, and sold NaturaLyte and GranuFlo in the state of Alabama.

82. At all times material hereto, Defendants Fresenius had a duty to exercise reasonable care in the design, manufacture, testing, research and development, processing,

advertising, marketing, labeling, packaging, distribution, promotion and sale of NaturaLyte and GranuFlo.

83. Defendant DaVita negligently mixed, distributed, promoted, marketed, advertised, and sold NaturaLyte and GranuFlo in the state of Alabama.

84. At all times material hereto, Defendant DaVita had a duty to exercise reasonable care in the mixing, distribution, promotion, marketing, advertising, and sale of and NaturaLyte and GranuFlo.

85. Defendants breached their duty and were wanton and reckless in their actions, misrepresentations, and omissions toward the Plaintiff in the following ways:

a. Failing to test and inspect NaturaLyte and GranuFlo in a reasonable manner in order to ascertain whether or not it was safe and proper for the purpose for which it was designed, manufactured, delivered, and sold;
b. Defendants Fresenius failing to utilize and implement a reasonably safe design in the manufacture of NaturaLyte and GranuFlo;
c. Defendants Fresenius failing to manufacture NaturaLyte and GranuFlo in a reasonably safe condition;
d. Failing to warn the Plaintiff of the danger of heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions from the use of NaturaLyte and GranuFlo;
e. Failing to label NaturaLyte and GranuFlo reasonably so as to warn the Plaintiff of the danger of heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions from the use of NaturaLyte and GranuFlo;
f. Defendants Fresenius manufacturing NaturaLyte and GranuFlo, which are unreasonably dangerous and defective hemodialysis products; and
g. Failing to insure DaVita clinicians, nurses, and/or physicians were adequately trained, instructed, credentialed, and prepared for proper use of all hemodialysis products in a manner that was safe and effective.

86. Defendants knew that NaturaLyte and GranuFlo had unreasonably dangerous risks and caused serious side effects of which the Plaintiff would not be aware. Defendants nevertheless advertised, marketed, sold, labeled, distributed, and instructed/trained on the use of

NaturaLyte and GranuFlo knowing that there were safer methods and products for dialysis treatment.

87. As a direct and proximate result of the wanton and reckless actions and inactions of the Defendant as set forth above, Johnny Williams sustained injuries and died.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiff demands judgment of the Defendants, Fresenius and DaVita, for damages in an amount determined by the jury and such other and further relief as allowed in equity or law.

COUNT VII
FRAUD, MISREPRESNTATION, AND SUPPRESSION

88. Plaintiff adopts and incorporates by reference all the allegations above.

89. Defendants Fresenius fraudulently, intentionally and/or negligently misrepresented to the Plaintiff, the FDA, and general public, the safety of NaturaLyte and GranuFlo and/or fraudulently, intentionally and/or negligently concealed material facts including adverse information regarding the safety of NaturaLyte and GranuFlo.

90. Defendants Fresenius made misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that NaturaLyte and GranuFlo had defects, dangers, and characteristics that were other than what the Defendants had represented to the FDA, and the consuming public, including the Plaintiff. Specifically, the Defendants misrepresented to the Plaintiff, the FDA, and the consuming public that:

a. NaturaLyte and GranuFlo, when used as recommended, were safe for use in dialysis treatments.
b. NaturaLyte and GranuFlo were fully and adequately tested.
c. NaturaLyte and GranuFlo had no serious undisclosed adverse effects on blood pressure, the heart, or cardiopulmonary physiology.
d. NaturaLyte and GranuFlo were safe and effective.

91. Defendants Fresenius knew or should have known that these representations were false and that the Plaintiff would rely on them, leading to the use of NaturaLyte and GranuFlo. Defendants Fresenius knew that physicians, dialysis clinicians, and nurses had been told the same false and fraudulent information about NaturaLyte and GranuFlo, and that the Plaintiff and the treating physicians, dialysis clinicians, and nurses would rely on information, advertisements and statements made by Defendants Fresenius about the use, safety and efficacy of NaturaLyte and GranuFlo.

92. At the time of Defendants' fraudulent misrepresentations and active concealment, the Plaintiff was unaware of the falsity of the statements being made and believed them to be true.

93. Johnny Williams justifiably relied on and/or was induced by the misrepresentations made by Defendant of the safety and use of NaturaLyte and GranuFlo, and in fact, used NaturaLyte and GranuFlo as recommended.

94. Defendants Fresenius concealed the truth from the Plaintiff and the consuming public about the real safety and risks of NaturaLyte and GranuFlo.

95. Defendants Fresenius had a post-sale duty to warn Plaintiff and the public about the potential risks and complications associated with NaturaLyte and GranuFlo in a timely manner.

96. The misrepresentations and active concealment by the Defendants Fresenius constitutes a continuing tort against Johnny Williams.

97. As a direct and proximate result of the misrepresentations and concealment of the Defendant as set forth above, Johnny Williams sustained injuries and died.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiff demands judgment of the Defendants Fresenius for damages in an amount determined by the jury and such other and further relief as allowed in equity or law.

COUNT VIII
WRONGFUL DEATH

98. Plaintiff adopts and incorporates by reference all the allegations above.

99. As a direct and proximate result of Defendants' negligence and otherwise culpable acts described herein, the Decedent, Johnny Williams, received GranuFlo which caused him to sustain injuries and damages outlined herein and caused his death.

100. Johnny Williams' injuries and death as alleged more fully herein directly resulted from Defendants' negligent and otherwise culpable acts, omissions, and/or misrepresentations.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiff demands judgment of the Defendants, Fresenius and DaVita, for damages in an amount determined by the jury and such other and further relief as allowed in equity or law.

COUNT IX
UNJUST ENRICHMENT

101. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

102. At all times relevant to this action, Defendants designed, advertised, marketed, promoted, manufactured, distributed, supplied, and/or sold NaturaLyte and GranuFlo.

103. Plaintiff and/or the decedent purchased NaturaLyte and GranuFlo for dialysis.

104. Defendant has accepted payment from Plaintiff and/or the decedent for the purchase of NaturaLyte and/or GranuFlo.

105. Plaintiff and the decedent did not receive the safe and effective pharmaceutical product intended.

106. It is inequitable and unjust for Defendants to retain this money because the neither the Plaintiff nor the decedent receive the product Defendants represented NaturaLyte and GranuFlo to be.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiff demands judgment of the Defendants, Fresenius and DaVita, for damages in an amount determined by the jury and such other and further relief as allowed in equity or law.

CLAIM FOR DAMAGES

WHEREFORE, the above premises considered, Plaintiff prays for judgment against Defendants, as follows:

a. For punitive damages in an amount to be proven at the time of trial;

b. For costs of this suit and attorneys' fees; and

c. All other relief that Plaintiff may be entitled to at equity or at law.

PLAINTIFF DEMANDS A TRIAL OF ALL ISSUES BY STRUCK JURY.

Date: July 27, 2012

Jon C. Conlin
ASB-7024-J66C
Kristian Rasmussen
ASB-1068-R64R
Alyssa Daniels
ASB-4207-J71N

Attorneys for Plaintiff
CORY, WATSON, CROWDER & DEGARIS, P.C.
2131 Magnolia Avenue, Suite 200
Birmingham, Alabama 35205
Telephone: (205) 328-2200
Facsimile: (205) 324-7896
E-Mail: jconlin@cwcd.com
krassmussen@cwcd.com
adaniels@cwcd.com